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EXAMINER

SHEIKH, HUMERA N

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Please find below and/or attached an Office communication concerning this application or proceeding.

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/842,466
Filing Date: April 26, 2001
Appellant(s): KOKUBO ET AL.

Timothy J. Balts
Reg. No. 51,429
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 02 September 2008 appealing from the Office action mailed 04 April 2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

4,820,524	BERTA	04-1989
6,406,738	HOGAN et al.	06-2002

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

- **(A) Claims 6-9, 11, 13-20 and 31-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berta (U.S. Pat. No. 4,820,524) in view of Hogan *et al.* (hereinafter “Hogan”) (U.S. Pat. No. 6,406,738):**

Berta (‘524) teaches a solid, multi-colored medicament preparation having a multi-colored gelatinous coating, wherein the coating layer provides two or more different colors (see reference col. 4, lines 5-42). The medicament may be in the form of a caplet and contains a layer of gelatin as a single coating on the caplet core (col. 4, lines 43-56).

Berta also teaches a method for coating the solid cores, such as caplets, to produce simulated, capsule-like medicaments. Berta teaches that one objective of the invention is to provide a simulated, capsule-like medicament having a gelatinous coating capable of being provided in two or more colors. Another objective is to provide a heavy layer of gelatin as a

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single coating to cover imperfections inherent on the caplet core (col. 4, lines 12-56). During the drying process, the caplet may be rotated to assist in uniformly distributing gelatin during drying (col. 5, lines 46-65). Suitable coatings to be used are gelatinous materials, such as methyl cellulose, calcium alginate and gelatin. Additional ingredients disclosed include plasticizers, preservatives, coloring agents and opacifying agents (col. 8, lines 20-47).

Berta teaches a solid, multi-colored medicament wherein colorings can be added to the coatings to produce opaque or transparent colors, such as red, white, pink, green, reddish brown, blue, yellow and black, for example. To form white medicaments or an opaque colored coating, titanium dioxide is often added to the gelatin (col. 9, lines 1-7). Berta teaches that first and second ends of the caplet can be coated with gelatinous coatings of different colors to provide a distinctive appearance for specialty products (col. 9, lines 3-5); (col. 10, lines 29-62). Berta teaches that the solid, multi-colored medicament preparation additionally comprises various coating patterns (see Figs. 8 a-d and col. 5, lines 28-29). Berta does not explicitly teach a logo, letters or a bar code on the medicament. However, the inclusion of logos, bar codes or letters, as instantly claimed does not make the invention patentable since variations in designs or patterns in solid medicament forms is commonly and routinely practiced in the pharmaceutical art.

Berta teaches a solid preparation comprising a gelatinous coating that provides two or more colors wherein the medicament is smooth, shiny, multi-colored and has various coating patterns. These medicaments are pleasing to the eye, are easier to swallow than prior medicaments and offer a distinctive appearance, as similarly desired by the applicant.

Berta does not teach “exposing a first part of the coating layer to a first amount of radiation and exposing a second part of the coating layer to a second amount of radiation under

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conditions sufficient to result in the first and second parts of the coating layer having different coloration”. However, this limitation does not impart a patentable distinction over the reference teachings of Berta. A product is being claimed in which the solid preparation comprises more than one distinct coloring agent. It is the position of the Examiner that the prior art expressly teaches a multi-colored, tablet formulation consisting of a first and second different coloring agents, wherein the tablet is provided with a single, multi-colored continuous coating layer. The instant claims are product claims and it is the patentability of the product that must be established, *per se*. Applicants have not demonstrated any unexpected or surprising results that accrue from the multi-colored, continuous film coating layer as claimed. “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

In this instance, the process of preparing the solid preparation does not afford patentable weight to the claims since Berta explicitly recognizes and teaches a solid medicament comprising a multi-colored, capsule-like coating, which is effective and aesthetically pleasing. The capsule-like medicaments have smooth, shiny, multi-colored gelatinous coatings thereon that are pleasing to the eye, easier to swallow and provide greater tamper resistance than conventional capsules.

In any event, **Hogan *et al.* (‘738)** are relied upon for the teaching of a powder coating composition for electrostatic coating of pharmaceutical substrates. Hogan teaches electrostatic

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coating of cores of pharmaceutical tablets with a powder coating material, whereby treatment of the powder to form a film coating preferably involves a heating step, using infra red radiation as well as other forms of electromagnetic radiation (see column 1, lines 1-19); (col. 4, lines 32-35). Alternatively, the powder material may include a polymer which is cured during the treatment, for example by irradiation with energy in the gamma, ultraviolet or radio frequency bands, to form a cross-linked polymer film. The change in the powder material during treatment may be from a solid to liquid and then, on cooling, to a continuous solid film (col. 4, lines 35-44). The powder material includes a first component which forms a good continuous coat over the surface of the substrate (col. 7, line 61 – col. 8, line 16). Preferably the powder coating material further includes one or more colorants, for example, metal oxides or lakes (col. 9, lines 57-61). A different colored coating may be formed on each of the opposite faces of the tablet (col. 12, lines 30-44).

Hogan teaches fusing of the powder to provide for a uniform coating. The energy is provided by focused radiation (col. 16, lines 16-24).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the powder coating material methods of Hogan, which comprise the step of employing radiation, within the multi-colored tablet of Berta. One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Hogan teaches that such a process would provide for a powder material having a good continuous coat over the surface of the substrate. The expected result would be an enhanced, multi-colored continuous coating layer having different colors along the body of the tablet for a pleasing colorful appearance for the consumer.

(10) Response to Argument (A):

Appellant argues, “The combination of references fails to disclose or suggest a solid preparation having a multi-colored continuous coating. Berta teaches a tablet having a multi-colored coating that is obtained by individually dipping and drawing first one end and then the other end of each tablet into a bath of gelatinous coating. Berta is not a single continuous coating. Berta does not disclose or suggest a solid preparation having a multi-colored continuous film coating layer as recited in independent claims 31 and 33.”

Appellant’s arguments have been considered, but were not found to be persuasive. Berta teaches a solid, multi-colored medicament preparation having a multi-colored gelatinous coating, wherein the coating layer provides for two or more different colors. See col. 4, lines 5-42. Berta teaches a solid, multi-colored medicament wherein colorings can be added to the coatings to produce opaque or transparent colors, such as red, white, pink, green, reddish brown, blue, yellow and black, for example. To form white medicaments or an opaque colored coating, titanium dioxide is often added to the gelatin See col. 9, lines 1-7. Berta further teaches that it is an objective of their invention to provide a layer of gelatin as a single coating to cover imperfections on the caplet core. See for instance, column 4, lines 54-56. The medicament in the form of a caplet contains a layer of gelatin as a single coating on the caplet core.

Appellant argues, “Hogan also fails to disclose or suggest a solid preparation having a multi-colored continuous film coating layer. The multi-colored coating of Hogan comprises two distinct coatings that are separately applied to the tablet.”

These arguments were not deemed convincing. The secondary reference of Hogan was relied upon for the teaching of the treatment of a powder film coating whereby heating, using infrared radiation is applied. The reference further teaches that other forms of electromagnetic radiation or conduction or induction may be used. See for instance, col. 4, lines 32-35. Furthermore, it should be noted that Hogan teaches a continuous solid film (col. 4, lines 35-44).

Appellant argues, "The combination of references also fails to disclose the step of selectively irradiating the continuous coating to produce a coating having two distinct colors. The references fail to disclose or suggest a process that can be used to prepare a solid composition having a multicolored continuous film coating layer."

Appellant's arguments were not rendered persuasive. Appellants are placing emphasis on the particular process by which they are formulating their multi-colored solid preparation. However, it should be kept in mind that the instant claims are not drawn to process or method claims but rather are drawn to *product-by-process* claims, whereby patentability is ultimately based on the product, *per se*. As delineated above, "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Appellants have not demonstrated any unexpected or superior results which would accrue from the solid preparation coated with a multi-colored, continuous film coating layer as claimed. The prior art amply recognizes and teaches solid preparations (*i.e.*, gelatin-coated caplets) as

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presently claimed, whereby the preparations are provided with a gelatinous coating that offers the use of two or more colors supplied with various coating patterns (see Berta).

Appellant argues, "One of ordinary skill in the art would not be motivated to irradiate the tablet of Berta because to do so would serve no purpose. The irradiation step in Hogan is necessary in order to melt and fuse the particles together in order to form a coating. Such a step is unnecessary in the process of Berta because the coating of Berta is provided as a liquid and as such there is no reason to apply irradiation to fuse the coating together as in Hogan."

The Examiner did not find this argument convincing. The issue here is whether the prior art suggests or highlights the advantages of employing irradiation in solid dosage formulations, which in this instance, clearly it does. The secondary reference of Hogan sufficiently demonstrates the use of irradiation methods provided in solid dosage formulations, such as tablets, whereby the reference further teaches cross-linking to yield different colors of the film coating layer. The reference teaches application of a coating provided over the entire surface of the tablet core (col. 12, lines 30-44); (col. 8, lines 14-16).

Appellant argues, "Neither Berta nor Hogan includes any teachings that their respective coatings would change color upon being irradiation. There is no basis for suggesting that the irradiation step of Hogan would result in changing the color of the coatings of either Berta or Hogan. The Office Action is using Applicants' own teachings in making this rejection. This is impermissible use of hindsight."

Appellant's arguments have been considered, but were not deemed persuasive. Hogan, as stated above, provides a method of treating a powder to form a film coating using radiation as a suitable means of treatment. Hogan states that the powder material may also include a

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polymer, which is cured during the treatment, for example by irradiation with energy in the gamma, ultra violet or radio frequency bands, to form a cross-linked polymer film. The argument that Appellant employs radiation for a different purpose than that of the prior art does not render a patentable distinction over the explicit teachings of the art. Moreover, a product is being claimed herein and not a method of irradiating solid materials. The instant claims merely require a solid provided with a coating layer have multiple (i.e., more than one) colors contained therein. Thus, the claims can be interpreted to even read on for example, a solid, such as an automobile that has more than one color or tint provided in the paint coat and thus would also read on the generic claims presented. Furthermore, the Examiner points out that, “[T]he reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant”. See, e.g., *In re Kahn*, 441 F.3d 977, 987, 78 USPQ2d 1329, 1336 (Fed.Cir. 2006).

In response to Appellant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Appellant argues, "It cannot be predicted how irradiation would affect the structure of the coatings of Berta. The irradiating step of Hogan in the process of Berta would result in the tablet being unsatisfactory for its intended purpose."

The Examiner respectfully disagrees. Whether an art is predictable or whether the proposed modification or combination of the prior art has a reasonable expectation of success is determined at the time the invention was made. *Ex parte Erlich*, 3 USPQ2d 1011 (Bd. Pat. App. & Inter. 1986). Moreover, "[T]he rationale to modify or combine the prior art does not have to be expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art, established scientific principles, or legal precedent established by prior case law". *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this instance, Appellant has not sufficiently demonstrated as to how the irradiation methods supplied by Hogan would be detrimental or adversary to the solid multi-colored formulation of Berta.

Appellant argues, "With respect to dependent claims 18-20 and 44-47, there is absolutely no teaching in either Berta or Hogan on how their respective teachings can be modified to produce a coating having a pattern, logo, bar code or letters."

This argument was not rendered persuasive. The inclusion of patterns, logos and bar codes, as stated in the Office Action, is routine practice in the art of formulating pharmaceutical tablets. While the combination references do not explicitly state the use of logos, patterns, or bar codes, the inclusion of such would provide for an aesthetically pleasing appearance as well as for easier identification of tablets, as is well known to one of ordinary skill in this art.

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Lastly, Appellant argues, "The Examiner has failed to understand the scope and contents of the prior art. Berta teaches a tablet having two coatings that are separately applied to separate halves of the tablet; Berta does not teach a continuous multi-colored coating. Similarly, Hogan also teaches providing a multi-colored coating by providing separate coatings on each half of the tablet."

The Examiner respectfully disagrees with Appellant's reasoning. Berta teaches a solid, multi-colored medicament preparation having a multi-colored gelatinous coating, wherein the coating layer provides for two or more different colors. See col. 4, lines 5-42. Berta further teaches providing a layer of gelatin as a single coating to cover imperfections on the caplet core (column 4, lines 54-56). The "single" coating taught by Berta would read on the "continuous" coating argued by Appellant, since a review of the instant specification does not set forth any specific definition for the term "continuous" as argued by Appellant. Thus, the "single" coating of Berta would be considered a uniform, uninterrupted coating. Appellant is attempting to highlight the particular process by which they are applying and obtaining the multi-colored continuous coating on their solid preparation. However, the Examiner reiterates the position that since the instant claims are drawn to product-by-process claims and not to process or method claims, the patentability of the product must be established herein and not the particular process by which the product was made or obtained. See *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) which states that, "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The secondary reference of Hogan was further relied upon to demonstrate the use of irradiation methods provided in solid dosage formulations (*i.e.*, tablets), whereby a coating is

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provided over the entire surface of the tablet core, to yield a continuous solid film (see column 4, lines 32-44 of Hogan). Thus, the secondary reference vividly addresses the use of irradiation as a means for supplying film coatings on solid preparations. In conclusion, it is the position of the Examiner that Appellants have not demonstrated that the solid, multi-colored formulations supplied by the combination of references would be materially different than that of the present invention. A reasonable interpretation of the instant claims indicates that they merely require a solid provided with a coating layer have multiple (*i.e.*, more than one) colors contained therein. As discussed above, Appellant's limitations would even read on a solid, (*i.e.*, an automobile) that has more than one color/tint (*i.e.*, metallic color) provided in the paint coat layer. Hence, for the reasons of record, the instant invention would be *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Humera N. Sheikh/

Primary Examiner, Art Unit 1615

Conferees:

/MP WOODWARD/

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